

### REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars:

1. Rejection under 35 U.S.C. §103(a)

With respect to the rejection of claims 1, 2, 4-7, and 10 under 35 U.S.C. §103(a) as being unpatentable over Fukuda (US 3,871,358) in view of Turnbull (US 5,996,582) and Gomez (US 6,053,166), Applicant respectfully traverses the rejection at least for the reason that Fukuda, Turnbull, and Gomez, combined or separately, fail to describe each and every limitation recited in the rejected claims.

Prior to address the above-summarized prior art rejection, Applicant would like to address the Examiner's improper interpretation of the claims as containing recitation of intended use.

Specifically, Applicant notes that the recitation "when guiding to the pharynx and retained there ..." has not been given patentable weight, as the Examiner contends such a language is directed to intended use and does not differentiate the claimed apparatus from prior art apparatus in Section 4 of the detailed Office Action. Applicant also notes that in Section 6 of the Office Action, the Examiner again contends that recitation of intended use in the claimed invention must result in a structural differences between the claimed invention and the prior art. In response, Applicant respectfully submits that the Examiner's contentions are erroneous for the following reasons:

As a common practice, statements reciting the purpose or intended use of a claimed invention generally would appear in a preamble of a claim. MPEP 2112.02 specifically addresses the issue of whether or not preamble recitations are structural limitations or mere statements of purpose or use. However, Applicants claimed limitations of guiding member engagement section, tubular engagement section, the guiding member alignment mark, and the tubular member alignment mark being in a particular position relative to each other as are not "intended use" statements. Rather, these are structural description, as well as functional

description, describing their cooperation in the invention, and the recitation of these features appears in the body of the claims and not in the preamble.

At this juncture, Applicant respectfully reminds the Examiner that there is nothing intrinsically wrong in defining something by what it does rather than what it is. MPEP §2173.05(g) and *In re Hallman* (CCPA 1981) 655 F.2d 212, 210 USPQ 609. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. In *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004). Hence, by the use of structural limitations as well as functional descriptions, Applicant's claims are in compliance with at least the guidelines set forth in MPEP §2173.05(g).

Applicant also notes that MPEP 2114 states, "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." [*emphasis added*] With this in mind, Applicant will now discuss the cited prior art and respectfully submits that, even if the functional description in the claims were not given patentable weight, the claimed structural limitations alone would distinguish over the cited prior art to Fukuda, Turnbull, and Gomez. In other words, Fukuda, Turnbull, and Gomez, combined or separately, fail to teach, disclose, or suggest each and every structural, as well as functional, limitation recited in the rejected claims.

As amended, independent claims 1 and 2 recite, among other features, the tubular member and the reinforcement element guiding the medical instrument to the digestive organ through the inner passageway such that when the guiding member engagement section is engaged with the tubular member engagement section, or when the guiding member alignment mark and the tubular member alignment mark are aligned with each other, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member.

When using Applicant's claimed supporting device for supporting insertion of a medical instrument into a human body, the guiding member is firstly inserted into the pharynx, and then the tubular member is inserted into the pharynx. If the tubular member is inserted too deeply, it may cause damage to the mucous membrane located at a deep

portion/position of the digestive organ. Therefore, when the tubular is inserted, not knowing the depth of insertion is a problem.

The presently claimed invention solves at least the above-mentioned problem. Particularly, according to Applicant's claimed invention, the guiding member has a smaller diameter than the tubular member, and, thus, the guiding member may be inserted easily into the tubular member. Further, for safety, desired insertion depth is easily determined by the use of the guiding member engagement section being engaged with the tubular member engagement section, or the guiding member alignment mark and the tubular member alignment mark being aligned with each other. As such, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member, and the claimed structure advantageously prevents the digestive organ end of the tubular member from being inserted too deeply. Accordingly, it is possible to carry out a safe operation.

With respect to Fukuda, the reference generally describes insertion of a single tube 1 into a digestive organ. Applicant respectfully asserts that the device of Fukuda is different from Applicant's claimed supporting device having a guiding member and a tubular member. The Examiner relies on the Turnbull and Gomez patents for allegedly teaching claimed features related to the guiding member that are missing from Fukuda. However, Applicant respectfully asserts that Turnbull and Gomez, combined or separately, fail to make up for the deficiencies of Fukuda.

Turnbull is generally directed to a tracheal assembly having a tube 10 with a curve shaft 11 and a shield 20 that is slidable along the inside of the tube. The shield includes a curved stiff rod 21 with a stop 22 which limits the extent of insertion of the shield into the tube. Applicant respectfully submits that the stop 22 of Turnbull is a part of the shield and stiff rod, which are being inserted as a tool that expands when the shield is inserted beyond the patient end of the tube to protect the posterior wall of the trachea during a tracheostomy procedure, while the guiding member (i.e., element 4 or 5 in Fig. 1) and the tubular member (i.e., 2 in Fig. 1) of the presently claimed invention are a part of a support device for supporting the insertion of a medical instrument into a human body.

Moreover, Turnbull patent does not teach, disclose, or suggest about the ends of a guiding member and tubular member being coincident when engaged or aligned, as claimed. To the contrary, when the stop 22 and machine end 13 of the Turnbull assembly are engaged, the shield plate 23 at the end of the rod 21 extends well beyond the end 12 of the tubular member 10. In fact, the purpose the tube 10 is to provide a way to insert an expandable shield member into the airway (trachea) of a subject, and the shield can only expand and function as intended when rod 21 is inserted so the shield plate at the end extends past the end 12 (see, column 3, lines 12-20 of Turnbull). Thus, the Turnbull patent appears to *teach away* from the claimed structural features of coincident ends of the tubular member and guiding member when the engagement sections are engaged.

With respect to Gomez, the Examiner contends that Gomez describe alignment marks, 22, 26, and 30. However, as clearly described in Gomez, elements 22, 26, and 30 are introduction segments that provide a modification of curvature of intubation tube 80 intended to be inserted into a trachea. According to Gomez, an end of tube 82 extends out of the end of the tube 80. That is, Gomez does not teach, suggest or otherwise render obvious the inclusions of alignment marks on both a tubular member and a guiding member, much less the claimed features of digestive organ ends of these members being generally coincident when the marks are aligned with each other.

Furthermore, the Examiner's interpretation that the segments 22, 26 and 30 of the intubating assembly of Gomez are "alignment marks" is not believed reasonable when considering the plain meaning of this term as understood by one of ordinary skill in the art. Nor are the segments 22, 26 and 30 of the Gomez assembly relevant to claimed subject matter relating to alignment marks on a guiding member.

To establish a *prima facie* case of obviousness, the Examiner must consider all features recited in the claims. This consideration must show where the features are shown in prior art or otherwise provide an explanation why the claimed features as a whole would have been known or obvious. As pointed out above, the Examiner has failed to give proper consideration to all the features of claims 1 and 2, and thus also any claims depending from these claims.

In view of the amendment and arguments set forth above, Applicant respectfully requests reconsideration and withdrawal of the §103(a) rejection of claims 1, 2, 4-7, and 10.

4. Conclusion

In view of the amendments to the claims, and in further view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is requested that claims 1-2, 4-7, and 10 be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the Applicant's representative, the Examiner is invited to contact the undersigned at the numbers shown.

Further, while no fees are believed to be due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4525.

Respectfully submitted,

/Donald R. Studebaker/

Donald R. Studebaker

Registration No. 32,815

Studebaker & Brackett PC  
1890 Preston White Drive  
Suite 105  
Reston, Virginia 20191  
(703) 390-9051  
Fax: (703) 390-1277  
don.studebaker@sapatentlaw.com